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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,344	11/21/2005	Dirk Mertin	LeA 36165	9502

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EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
08/11/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/516,344	MERTIN ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/2010 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The declarations under 37 CFR 1.132 filed 6/22/2010 and 6/30/2010 are insufficient to overcome the rejection of claims 1, 3, 11-20 under 35 U.S.C. 103(a) as being unpatentable over US 5152986 ('986) in view of US 6323213 ('213).

Applicant argues the following points:

(1) The data and declaration of Dr. Heep shows that one of the thickeners mentioned by '986, silica, does not provide a thixotropic composition and have hardly any yield point. According, it would not have been obvious to prepare the formulation of the present invention without undue experimentation.

(2) Palatability is a particular problem with cats. Although '986 mentions that binding of quinolone to an ion exchanger masks bad taste, Applicant has discovered that their psuedoplastic gel formers add to the palatability. '986 does not specifically refer to the problem of preparing a liquid formulation with a particularly good mouthfeel and do not point out which pseudoplastic gel formers should be used in the solution to this problem. Furthermore, enrofloxacin is the quinolonecarboxylic acid that is typically used and well known in the veterinary field. Accordingly, someone skilled in the art would not find it predictable to use pradofloxacin rather than enrofloxacin without undue experimentation.

The Examiner appreciates the declaration of Dr. Iris Heep. However, Applicant's arguments and the declaration have been fully considered but are not found persuasive.

(1) The Examiner agrees that Formulation 1, which comprises xanthan, is thixotropic, and that Formulations 2-4, which comprise silica, is not thixotropic. The Examiner agrees that the results show that substituting xanthan for silica in the disclosed formulations results in an unexpectedly thixotropic formulation. To repeat, the results show that substituting xanthan for silica in the disclosed formulations results

in an unexpectedly thixotropic formulation. There are two reasons why the results are insufficient to overcome the current grounds of rejection:

(A) To overcome a rejection through a showing of unexpected results, there must be a nexus between the results and the claimed invention. Looking to the claimed invention, the liquid pharmaceutical preparation of claim 1 comprises pradofloxacin bound to an ion exchange resin, water, and a psuedoplastic gel former selected from polyacrylic acid, xanthan, microcrystalline cellulose, cellulose ether, bentonite, or mixtures thereof. Formulations 1-4 contain these components and additionally contain sorbic acid, ascorbic acid, propylene glycol, and vanilla flavor. Although claim 1 is open to inclusion of sorbic acid, ascorbic acid, propylene glycol, and vanilla flavor, these are not recited components of claim 1. By contrast, sorbic acid, ascorbic acid, propylene glycol, and vanilla flavor are required components to the results. In other words, the results show that substitution of xanthan for silica in a composition comprising pradofloxacin, Amberlite IRP 64, sorbic acid, ascorbic acid, propylene glycol, vanilla flavor, and water gives improved thixotropy. This is what the Examiner means by sorbic acid, ascorbic acid, propylene glycol, vanilla flavor are required components to the results. The results do not show that substitution of xanthan for silica in a composition comprising pradofloxacin, Amberlite IRP 64, and water (without sorbic acid, ascorbic acid, propylene glycol, vanilla flavor) necessarily gives an improved thixotropy. The Examiner notes that sorbic acid, ascorbic acid, and vanilla flavor are present in relatively small amounts in Formulations 1-4. For the sake of argument, if sorbic acid, ascorbic acid, and vanilla flavor were not required components to the results because

they are present in small amounts, propylene glycol is the main component present in Formulations 1-4 is a required component to the results. In summary, there is no nexus between the results and the claimed invention because the results are to formulations that comprise sorbic acid, ascorbic acid, propylene glycol, vanilla flavor, and the claims do not require these components. If the claims recited these components, then there would be a nexus between the results and the claimed invention.

(B) To overcome a rejection through a showing of unexpected results, the results must be commensurate in scope with the claimed invention. The presence of sorbic acid, ascorbic acid, propylene glycol, and vanilla flavor in Formulations 1-4, while absent from the claimed invention, is noted above. Additionally, the results are limited to xanthan as the psuedoplastic gel former and would not necessarily extend across the scope of the claimed invention. Particularly, the results for xanthan would not necessarily hold true for polyacrylic acid, microcrystalline cellulose, cellulose ether, and bentonite. These psuedoplastic gel formers have different molecular structures and chemical behaviors. Accordingly, the skilled artisan would not accept that the results shown for xanthan would necessarily extend to these pseudoplastic gel formers. Additionally, the results are to one ion exchange resin, Amberlite IRP 64. Ion exchange resins have vastly different molecular structures and chemical behaviors. Accordingly, the results for Amberlite IRP 64 would not necessarily extend across all ion exchange resins commensurate in scope with claim 1. In summary, the skilled practitioner would not accept that the results for Formulations 1-4 would hold true over the scope of claim

1, which encompasses polyacrylic acid, xanthan, microcrystalline cellulose, cellulose ether, and bentonite as pseudoplastic gel formers and any ion exchange resin.

(2) Applicant argues that certain thickeners (pseudoplastic gel formers) would not provide adequate yield points and shear viscosity. Applicant further argues that the art does not address the challenge of preparing a liquid formulation with a particularly good mouthfeel. The Examiner does not disagree that Applicant has made a good product with many desirable properties. The question at hand is whether Applicant's claimed product is obvious over the prior art. In other words, would it have been obvious at the time the instant invention was made to arrive at the same product as the one claimed. The Examiner maintains that the answer to this question is yes. '986 discloses ion exchange resins which are loaded with quinolonecarboxylic acid derivatives, and their preparation (see entire document; abstract; col 1, lines 9-11). The quinolonecarboxylic acids are bound to ion exchange resins, such as Lewatit® SPC 108 (an acidic ion exchange resin) and are dispersed in a aqueous carrier for administration to an animal (see col 5, lines 14-22). Bentonite (a pseudoplastic gel former) may be added to the formulation of '986 as an auxiliary agent (see col 5, lines 46-52; col 6, lines 34-37). Other pseudoplastic gel formers, such as xanthan gum, may be used to thicken the carrier into a semi-solid (a highly viscous liquid) (see col 6, lines 18-26). Although the recited thickeners are added so that the suspension may be administered as a semi-solid, a semi-solid is a highly viscous liquid. The Examiner notes that bentonites (a presently disclosed pseudoplastic gel former) may also be added to the formulation of '986 (with or without the presence of thickeners) as an

auxiliary agent (see col 5, lines 46-52; col 6, lines 34-37). Accordingly, '986 is deficient only in that it does explicitly teach pradofloxacin as the quinolonecarboxylic acid derivative. This deficiency is made up for by the teaching of '231. It would have been obvious to incorporate pradofloxacin as the quinolonecarboxylic acid in the formulation disclosed by '986, as pradofloxacin has a more potent antibacterial action than enrofloxacin and is suitable for human and veterinary medicine. That the art does not recognize the advantages of the formulation pointed out by Applicant does not distinguish Applicant's claimed invention from the prior art. "'[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

August 5, 2010